ROYAL ANTIBACTERIAL TROPICAL FRUIT HAND CLEANSE- triclos an gel Filo America

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient Purpose

Triclosan 0.15%......Antibacterial

 \Box Uses

for handwashing to decrease bacteria on the skin.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Wet hand, apply to hands, scrub thoroughly, Rinse.

□ Warnings

For external use only.

Avoid getting into eyes. If this happens, rinse thoroughly with water.

Wet hand, apply palmful to hands, scrub thoroughly, Rinse.

Inactive Ingredients

camphor, carbomer, ethyl alcohol, fd&c blue no.1, isopropyl alcohol, methylchloroisothiazolinone, methylisothiazolinone, sodium hydroxide, water, cocamide MEA, PEG-18 glycaryl





Drug Facts

Active Ingredient

Purpose

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..Antibacterial

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Directions: • Wet hands • Apply to hands • Scrub thoroughly • Rinse.

Inactive Ingredients: Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Glycerin, Sodium Chloride, Glyceryl Cocoate, Fragrance, Polyquaternium-7, Cocamide MEA, DMDM Hydantoin, Tetrasodium EDTA, Citric Acid, FD&C Yellow 5, FD&C Yellow 6.

*This product is not manufactured or distributed by Colgate-Palmolive Company, distributor of Softsoap® Brand Aquarium Series Antibacterial Soap.



Distributed by: FILO AMERICA P.O. Box 23592 Los Angeles, CA 90023 Made in China Questions or Concerns? 1.866.460.0322

ROYAL ANTIBACTERIAL TROPICAL FRUIT HAND CLEANSE

triclosan gel

Product Information

Product Type HUMAN OTC DRUG

Item Code (Source)

NDC:50438-108

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	1.5 mg in 1 mL

Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0KO0R) SODIUM C14-16 OLEFIN SULFONATE (UNII: 09W3D3YF5U) SODIUM LAURETH SULFATE (UNII: BPV390UAP0) COCO DIETHANOLAMIDE (UNII: 92005F972D)

SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50438-108-01	500 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	09/17/2013		

Labeler - Filo America (943873703)

Establishment						
Name	Address	ID/FEI	Business Operations			
Ningbo Pulisi Daily Chemical Products Co., Ltd.		529047265	manufacture(50438-108)			

Revised: 9/2013 Filo America